IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.*	:	**CIVIL ACTION**
HERBERT J. NEVYAS, M.D., and	:	
ANITA NEVYAS-WALLACE, M.D.	:	
	:	
v.	:	
	:	**NO. 09-432**
ALLERGAN, INC.	:	

MEMORANDUM

KEARNEY, J. **July 2, 2015**

Qui tam Realtors Herbert J. Nevyas, M.D. and Anita Nevyas-Wallace, M.D. ("Relators") sued Defendant Allergan, Inc. ("Allergan") under the False Claims Act, 31 U.S.C. §3729 *et seq.* ("FCA") and analogous false claims and whistleblower statutes of various states and the District of Columbia. Relators allege Allergan induced physicians to prescribe Allergan products, in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b) ("AKS"), causing pharmacists to submit "false or fraudulent" claims to government healthcare programs in violation of the FCA. After oral argument and consideration of the extensive briefing, including from the United States, the Court granted in part and denied in part Allergan's motion to dismiss in our May 26, 2015 Order.

Disagreeing with our Order, Allergan now moves to certify the Court's May 26, 2015 Order for interlocutory review pursuant to 28 U.S.C. § 1292(b). We find Allergan's disagreement, even if characterized as "substantial," does not warrant piecemeal litigation through an interlocutory appeal. Allergan does not sufficiently demonstrate substantial grounds for a difference of opinion on the pharmacist certifications and scienter issues required for the "exceptional circumstance" of an interlocutory appeal.

I. Procedural History

Relators filed their Second Amended Complaint ("SAC") under seal on September 27, 2010. (ECF Doc. No. 15.) This Court unsealed the action in December 2013. (ECF Doc. No. 42.) The United States declined to intervene but remains a party in interest. On April 29, 2014, Allergan moved to dismiss the SAC for failure to state a claim upon which relief may be granted under Fed.R.Civ.P. 8 and 12(b)(6), and for failure to plead fraud with particularity under Fed.R.Civ.P. 9(b). (ECF Doc. No. 62.) After several rounds of briefing, we held oral argument on April 23, 2015.

Allergan moved to dismiss focusing on the falsity of pharmacists' certifications and the related question of Allergan's scienter under the FCA. On the "falsity" issue, Allergan, relying on a 2011 opinion from our Court of Appeals in *U.S. ex rel. Wilkins v. United Health Group, Inc*,.[1] urged dismissal of the Relators' claims because the FCA does not apply where *pharmacists*, unaware of Allergan's alleged scheme, certified compliance with the AKS, a material condition of payment under federal healthcare programs, when submitting claims for payment on prescriptions allegedly tainted by kickbacks between Allergan and prescribing physicians. On the "scienter" issue, Allergan argued Relators failed to adequately plead it "knowingly" caused the submission of false claims as submitted by pharmacists, and Allergan cannot have acted "knowingly" where it "adopted a reasonable interpretation" of the AKS and "related regulatory guidance." Our May 26, 2015 Order rejected these arguments finding, *inter alia*, Relators' FCA claims are not foreclosed by *Wilkins* and Relators sufficiently alleged scienter at the motion to dismiss stage. (ECF Doc. No. 100.)

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[1] 659 F.3d 295 (3d Cir. 2011) ("*Wilkins*").

II. Analysis – Interlocutory Review Under 28 U.S.C. §1292(b)

Allergan seeks interlocutory review of the Court's decision on two issues:

1. "Whether, under [*Wilkins*,] a pharmaceutical company's alleged payment of kickbacks to prescribing physicians can render truthful certifications by pharmacists (who did not receive the alleged kickbacks) of their own compliance with the [AKS] "legally false" for purposes of the [FCA];" and

2. "Whether, under *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007), based on the legal and regulatory guidance available during the period in question, it was objectively reasonable, or at least not reckless, to conclude that a pharmacist's truthful certification of compliance with the AKS could not be legally false for purposes of the FCA, such that Allergan lacked the requisite state of mind to violate the FCA as a matter of law."

Allergan's Motion at 2. (ECF Doc. No. 102-1.)

Interlocutory appeals should be reserved for "exceptional cases." *Caterpillar Inc. v. Lewis*, 519 U.S. 61, 74 (1996) (quotation marks and citation omitted). A district court may certify an order for interlocutory appeal where it is "of the opinion that such order:" (1) "involves a controlling question of law;" (2) "as to which there is substantial ground for difference of opinion;" and (3) "an immediate appeal from the order may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b); *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 754 (3d Cir. 1974).

The decision to certify an order for appeal under §1292(b) is within our discretion. *Glaberson v. Comcast Corp.*, No. 03-6604, 2006 WL 3762028, at *12 (E.D. Pa. Dec. 19, 2006) (citation omitted); *see also U.S. ex rel. Galmines v. Novartis Pharm. Corp.*, No. 06-3213, 2013 WL 4511626, *2 (E.D. Pa. Aug. 26, 2013) (citing *Bachowski v. Usery*, 545 F.2d 363, 368 (3d Cir. 1976)). It is appropriate only in "exceptional circumstances" and "[we] should be mindful of the strong policy against piecemeal appeals when exercising [our] discretion." *Glaberson*, 2006 WL 3762028, at *12 (citation omitted). The burden is on the party seeking certification to

demonstrate "exceptional circumstances justify a departure from the basic policy against piecemeal litigation and of postponing appellate review until after the entry of a final judgment." *Burlington v. News Corp.*, No. 09-1908, 2015 WL 158746, *3 (E.D. Pa. Jan. 12, 2015) (quoting *Hall v. Wyeth, Inc.*, No. 10–738, 2010 WL 4925258, *1 (E.D.Pa. Dec. 2, 2010)).

Allergan argues all three factors for certification under §1292(b) are met here but focuses its argument mainly on the second element, asserting there is "substantial ground for difference of opinion" on both the pharmacists certifications and scienter issues. The second element is met when the matter involves "one or more difficult and pivotal questions of law not settled by controlling authority." *Hall v. Wyeth, Inc.,* No. 10-738, 2010 WL 4925258, *2 (E.D.Pa. Dec. 2, 2010) (citation omitted). "Substantial grounds for difference of opinion" may also exist "where there is genuine doubt or conflicting precedent as to the correct legal standard," "conflicting and contradictory opinions," or "the absence of controlling law on a particular issue." *Id.* (citations omitted).

Even assuming this case involves a controlling question of law and an immediate appeal from the Order may materially advance the ultimate termination of this matter, Allergan has not sufficiently demonstrated there exists "substantial grounds for difference of opinion" on the pharmacist certifications and scienter issues.

A. Pharmacists' Certifications

Attempting to re-litigate the issue raised in its Motion to Dismiss, Allergan contends kickback-tainted claims submitted by innocent pharmacists cannot be "false" under the FCA. Allergan argues our Court of Appeals "has not yet definitively resolved" whether truthful certifications made by innocent pharmacists give rise to an FCA claim, and three decisions

outside the Third Circuit create "conflicting and contradictory opinions" sufficient to establish "substantial grounds for difference of opinion."

We do not agree there is an absence of controlling law simply because our Court of Appeals has not addressed the specific factual scenario Allergan raises regarding certifications by innocent pharmacists. *See e.g. Cuttic v. Crozer-Chester Med. Ctr.,* 806 F. Supp. 2d 796, 805 (E.D. Pa. 2011) (citing *Shaup v. Frederickson*, No. 97–7260, 1998 WL 800321, at *3 (E.D.Pa. Nov. 17, 1998) ("If questions of first impression alone were sufficient to warrant certification for an immediate appeal, our Court of Appeals would be besieged with piecemeal interlocutory appeals.")).

We read *Wilkins* and *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004) ("*Schmidt*") as guidance for the following principles:

- In *Wilkins*, our Court of Appeals recognized "Congress' expressly stated purpose that the FCA should 'reach all fraudulent attempts to cause the Government to pay [out] sums of money or to deliver property or services.' " *Wilkins*, 659 F.3d at 306 (citation to Senate Report omitted);

- Compliance with the AKS is a condition of payment by government healthcare programs, and claims submitted in violation of the AKS are "false" for purposes of the FCA. *Wilkins*, at 313-314; *Schmidt*, 386 F.3d at 243; and

- Defendants who knowingly *cause* the submission of false claims may be liable under the FCA; the "knowledge and conduct of the defendant [is] what matter[s] and the outcome [does] not turn on whether the actual presenters were 'duped' or participated in the fraudulent scheme." *Schmidt*, 386 F.3d at 243-244 (footnoted omitted).

Applying these principles, we found Relators adequately alleged Allergan induced physicians to write kickback-tainted prescriptions for its products filled by pharmacists and, as a natural consequence of the scheme, Allergan "caused to be presented" "false or fraudulent" claims to the United States. *See* May 26, 2015 Order at 2, n.1 (ECF Doc. No. 100.) We find no

support for the proposition our Court of Appeals has left unanswered the question of whether this type of conduct is actionable under the FCA.

Wilkins is not "contrary legal authority" to *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377 (1st Cir. 2011) ("*Hutcheson*"). Allergan's argument hinges on one "*but see*" signal in the *Wilkins* opinion. The use of the "*but see*" signal simply acknowledged the First Circuit Court of Appeals declined to employ "judicially created categories of express and implied false certification." *Wilkins*, 659 F.3d at 306. We do *not* read this signal as "contrary legal authority" to *Wilkins*.[2] Allergan failed to offer any decision by our Court of Appeals or any district court within this Circuit holding otherwise.

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[2] In reaching its holding that a non-submitting defendant may be liable if it causes a third party to submit false or fraudulent claims under the FCA, the First Circuit in *Hutcheson* relied, in part, on two Supreme Court cases: *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) ("*Hess*") and *United States v. Bornstein*, 423 U.S. 303 (1976) ("*Bornstein*"). *Hutcheson*, 647 F.3d at 390. In rejecting the argument Allergan advances here, the First Circuit, citing both *Hess* and *Bornstein*, stated:

> The Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim, and it has not conditioned this liability on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct.
> . . .
> These cases do not hold that a submitting entity's representations concerning its own conduct somehow immunize a non-submitting entity from liability under the "causes" clauses of the FCA. Nor does [defendant] cite any other decision from the Supreme court [sic] or this court that says that.

Id.

Notably, the Third Circuit in *Schmidt* also cited both *Hess* and *Bornstein*, finding:

> It does not appear from the opinion of the Court in either *Hess* or *Bornstein* that the party actually presenting the claims to the government was aware of the fraudulent conduct. This was not a matter material to the Court's analysis, however. Given the Court's view that the crucial issue was whether the defendants knowingly assisted in the presentation of false claims, the knowledge and conduct of the defendant were what mattered and the outcome did not turn on

The three district court decisions cited by Allergan – *Rost*, *Bailey*, and *Hutcheson*[3] - do not create "substantial grounds for difference of opinion." The three cases are not "conflicting and contrary decision[s]" in the Third Circuit. To the contrary, we find our Court of Appeals' *Schmidt* decision supports FCA liability on any person who "knowingly presents, or *causes to be presented*, a false or fraudulent claim for payment or approval." 31 U.S.C. §3729(a)(1)(A) (emphasis added).[4]

A divergence of holdings among *Rost*, *Bailey*, and *Hutcheson* (D.Mass.) and *Schmidt* does not require "guidance" from our Court of Appeals. The First Circuit reversed *Hutcheson* (D.Mass.), which is no longer the law in that Circuit. In the wake of the First Circuit's reversal of *Hutcheson* (D.Mass.), we find questionable the validity of *Rost* for the proposition advanced by Allergan in its motion to dismiss.[5] The 2010 amendment to the AKS through the Patient

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> whether the actual presenters were "duped" or participated in the fraudulent scheme. Accordingly, we believe the District Court erred in concluding that someone other than the actual presenter cannot be responsible under the FCA in the absence of duping.

Schmidt, 386 F.3d at 243-244 (footnote omitted).

We find the similarity in the analysis of both the First Circuit and Third Circuit, and the respective Courts' reliance and citation to *Hess* and *Bornstein* in support of its analyses, as further support for our finding there is no "substantial grounds for difference of opinion" between *Wilkins* and *Hutcheson*.

[3] *U.S. ex rel. Rost v. Pfizer, Inc.*, 736 F.Supp. 2d 367 (D.Mass. 2010) ("*Rost*"); *U.S. ex rel. Thomas v. Bailey*, No. 06-0465, 2008 WL 4853630 (E.D.Ark. Nov. 6, 2008) ("*Bailey*"); and *Hutcheson v. Blackstone Medical, Inc.*, 694 F.Supp. 2d 48 (D.Mass. 2010), *rev'd*, 647 F.3d 377 (1st Cir. 2011) (hereafter "*Hutcheson* D.Mass.").

[4] Relators' SAC refers to the pre-FERA version of the FCA at 31 U.S.C. § 3729(a)(1) and (2).

[5] Although the First Circuit's opinion in *Hutcheson* did not expressly overrule *Rost*, we find no cases applying *Rost* in the way Allergan suggests, and Allergan did not provide us with any, after *Hutcheson* (First Circuit).

Protection and Affordable Care Act ("PPACA") superseded the *Bailey* case. While the PPACA does not apply retroactively, we find Congress, in amending the AKS, intended "*to clarify* that a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].' " *Wilkins*, 659 F.3d at 311 n. 19 (quoting 42 U.S.C. § 1320a-7b(g)) (emphasis added). Moreover, we do not agree with the import of Allergan's argument on this point, which we read to suggest its alleged conduct prior to the AKS amendment was lawful and cannot constitute a violation of the FCA.[6] As explained here and in

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[6] We find persuasive the reasoning in *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F.Supp.2d 39, 52 (D.Mass. 2011), where the court, citing *Wilkins*, rejected any notion the amended AKS *changed* rather than *clarified* liability under the FCA:

> The amendment's legislative history, however, evinces Congress' intent to clarify, not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act. Senator Ted Kaufman stated that the PPACA's purpose was to "ensure that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves" and to "strengthen [ ] whistleblower actions based on medical care kickbacks" "[b]y making all claims that stem from an illegal kickback subject to the False Claims Act." 155 Cong. Rec. S10852, S10853 (daily ed. Oct. 28, 2009) (Sen. Kaufman). The Senator identified the specific impetus for the amendment as (1) "remed[ying]" a then-recent district court decision that had "defeat[ed] legitimate [False Claims Act] enforcement efforts," and (2) adopting the "success[ful]" position that the Department of Justice consistently has advanced in "pursuing False Claims Act matters based on underlying violations of the Anti–Kickback Statute." *Id.* (Sen. Kaufman). Because the intent of Congress is to be culled from the events surrounding the passage of the PPACA, *see Securities & Exch. Comm'n v. Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 199–200, 84 S.Ct. 275, 11 L.Ed.2d 237 (1963), **Senator Kaufman's comments, made in advance of the PPACA being signed into law, reliably suggest that the amendment was intended not to create a new basis for liability but to clarify the reach of the Anti–Kickback Statute, which had been called into question by recent litigation**. *See also Wilkins*, 659 F.3d 295 at 311 n. 19 (using the word "clarify" to describe the effect of this recent amendment to the Anti–Kickback Statute).

Westmoreland, 812 F.Supp.2d at 52-53 (footnote omitted) (emphasis added). *See also U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 332-35 (S.D.N.Y. 2014) (discussing the legislative history of the PPACA amendment to the AKS).

our May 26, 2015 Order, compliance with the AKS is a material condition of payment under federal health programs, false certification of compliance is actionable under the FCA, and defendants who "cause to be presented" false claims are liable under the FCA. This is entirely consistent with our reading of *Schmidt*, which pre-dates the amendment to the AKS, and *Wilkins*.[7] Thus, we do not see *Rost*, *Bailey*, and *Hutcheson* (D.Mass.) – all decisions from outside this Circuit and, in any case, not valid authority even in their own Circuits now – creating "substantial ground for difference of opinion" in this Circuit.

Allergan's motion for certification attempts to re-litigate issues presented in its Motion to Dismiss. "Strong disagreement" with our Order and its application of the law to the facts alleged here does not constitute a "substantial ground for difference of opinion." *Sobek,* 2013 WL 3852795 at *1. This disagreement does not warrant an interlocutory appeal. *See Mullen v. Norfolk Southern Ry Co.*, No. 13-6348, 2014 WL 2587017, *2 (E.D.Pa. June 9, 2014) (citation omitted); *see also U.S. ex rel. Sobek v. Education Management, LLC*, No. 10-131, 2013 WL 3852795, *2 (W.D. Pa. July 23, 2013) ("the Court is *not* persuaded that this case is so different that a piecemeal appeal should be permitted" and "the ultimate merits of [defendant's] arguments may benefit from the fuller evidentiary record developed during discovery.")

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[7] We similarly reject Allergan's argument regarding our citation to *U.S. ex rel. Cairns v. D.S. Medical LLC*, No. 12-4, 2015 WL 590325 (E.D. Mo., Feb. 11, 2015) and *U.S. ex rel. Brown v. Celgene Corp.*, No. 10-3165, 2014 WL 3605896 (C.D. Ca. July 10, 2014) as persuasive authority.

B. Scienter

We also find no "substantial ground for a difference of opinion" in this Circuit on the sufficiency of Relators' pleading of Allergan's state of mind based on the *Streck*[8] case or because our Court of Appeals "has yet to [address]" whether pharmacists' certifications are "false." We do not read the *Streck* decision to have "reached a conflicting outcome" with our May 26, 2015 Order on the sufficiency of Relators' *pleading* Allergan's state of mind.

In *Streck*, another judge in this District relying on Supreme Court precedent at the summary judgment stage dismissed claims for a certain period of time against defendants because, under the facts as alleged there, the court found "there was nothing that 'warned' [defendants] away from the view [they] took' " on an interpretation of regulations calculating Average Manufacturer Price allegedly fraudulently reported to the Government. *Streck*, 894 F.Supp. 2d at 596 (quoting *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 (2007)).

We found Relators alleged facts "plausibly showing" Allergan's required state of mind for an FCA claim. We cited to Relators' SAC alleging, *inter alia*, Allergan caused to be submitted false claims through its scheme to induce physicians to prescribe Allergan products; eye care physicians who received Allergan's illegal inducements directed referrals of patients in federally-funded health care programs to Allergan products in violation of the AKS and similar state statutes; when Allergan intentionally employed illegal kickbacks to promote its products, it knew or should have known pharmacists and physicians would routinely and necessarily file false and fraudulent claims with federal and state governments. *See* May 26, 2015 Order at 2 n.1 (ECF Doc. No. 100.) We found Relators made sufficient allegations to plausibly show Allergan acted with "knowledge," as defined by the FCA, to induce physicians through illegal kickbacks

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[8] *U.S. ex rel. Streck v. Allergan*, 894 F.Supp. 2d 584 (E.D. Pa. 2012).

to write prescriptions for Allergan products which would, as a natural consequence of the scheme, cause those prescriptions to be presented for payment by government funded healthcare programs.

In *Streck*, the court found otherwise in a different fact pattern, focusing its consideration of the "regulatory framework in deciding whether there are sufficient facts to plausibly show Defendants had the required state of mind." *Id.*, at 600 n.11. Although the court in *Streck* found that scienter was not sufficiently plead *under the facts of that case*, it does not create a "substantial ground for a difference of opinion" justifying an interlocutory appeal here. Relators have specifically pled knowledge; they have the ability in discovery to determine the extent, if any, of Allergan's knowledge of case law in other Circuits and the effect, if any, of applicable regulations.[9]

We find Allergan's interpretation of the law focuses on its state of mind, and is properly addressed after full development of the factual record. Allergan's reasonable interpretation of the law and applicable regulatory framework may well be a defense to liability, but it is not appropriate at the motion to dismiss stage when there are reasonable interpretations to the contrary. At any rate, Allergan's arguments do not present "exceptional circumstances [to] justify a departure from the basic policy against piecemeal litigation and of postponing appellate review until after the entry of a final judgment." *Burlington, supra*, 2015 WL 158746 at *3.

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[9] Allergan relies on conclusory regulatory guidance when the Relators dispute the conclusions. For example, Allergan's cited regulatory guidance addresses programs specifically tied to support the purchased product and services without substantial value to the purchaser. Relators argue, under the same regulatory guidance, Allergan's services or programs confer a benefit and do not support the purchased product. *See e.g.* SAC ¶¶ 103, 159, 161, 167, 174, 175, 181, 185, 189-91, 193-96. We cannot now determine whether Allergan "ran a risk of violating the law substantially greater than the risk associated with a reading that was merely careless." *Safeco*, 551 U.S. at 69. These are disputed issues of state of mind subject to discovery.